510 (k) Summary

K140042

APR 1 0 2014

Submitter's information:

Name: LeMaitre Vascular, Inc.
Address: 63 Second Avenue
Burlington, MA USA 01803
Phone: 781-425-1729

Contact Person: Xiang (Vic) Zhang

Date of preparation: January 6, 2014
Device Name: 1.5mm HYDRO Expandable LeMaitre Valvulotome
Trade Name. HYDRO Expandable LeMaitre Valvulotome
Common/ Classification Name: Valvulotome, External Vein Stripper

Classification Panel: 21CFR §870.4885
Class: II (2)

Product Code: MGZ
Classification Panel: Cardiovascular

Establishment Registration: 1220948

Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803

Proposed Subject Device Description:

The 1.5mm HYDRO Expandable LeMaitre Valvulotome is a self-centering and self-sizing valvulotome device used for cutting vein valves. The centering hoops keep the device centered in the vein. The size of the centering hoops and cutting blades adjust to the internal diameter of the vein as the valvulotome is being drawn through the vessel cutting the valves and rendering them ineffectual. The modifications to the predicate device - Expandable LeMaitre Valvulotome (ELV)- include the addition of hydrophilic coatings and co-extruded sheath to create 1.5mm HYDRO Expandable LeMaitre Valvulotome. The hydrophilic coatings provide increased lubricity and allow the device to navigating veins easier.

Proposed Intended Use (Subject Device):

It is used for the treatment of vascular disorders, and more particularly for excising or disrupting venous valves.

Predicate Intended Use:

It is used for the treatment of vascular disorders, and more particularly for excising or disrupting venous valves.

Predicate Devices:

510(k):	K132190 (Change to indication)
Device Name:	Expandable LeMaitre Valvulotome, Over-the-Wire LeMaitre Valvulotome
SE Date:	8/5/2013
Regulation Number:	21CFR §870.4885
Device Class Name:	Valvulotome, External Vein Stripper
Device Class:	II
Product Code:	MGZ

510(k):	K980732
Device Name:	Expandable LeMaitre Valvulotome
SE Date:	2/12/1999
Regulation Number:	21CFR §870.4885
Device Class Name:	Valvulotome, External Vein Stripper
Device Class:	II
Product Code:	MGZ

Substantial Equivalence:

Fundamental Scientific Technological Characteristics:

The 1.5mm HYDRO Expandable LeMaitre Valvulotome maintains the same intended use and fundamental scientific technology as the predicate device(s) and is substantially equivalent to the predicate device(s).

Functional/ Safety testing:

The verification activities conducted on the subject device indicate that 1.5mm HYDRO Expandable LeMaitre Valvulotome meets the product performance specifications and the modifications do not raise any additional safety issues.

Sterilization:

The device is validated for ethylene oxide (EO) sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization". The Sterilization process remains unchanged.

Biocompatibility:

All blood contact portions of the device were subjected to Biocompatibility testing according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), with circulating blood. The biocompatibility assessment established that 1.5mm HYDRO Expandable LeMaitre Valvulotome is biocompatible.

Summary of Product Testing:

The following tests have been completed to evaluate the performance of the Subject Device:

- Dimensional Verification
- Fatigue Testing
- Flushability
- Force to insert and remove device
- Force to open and close device
- Tortuous Sheathing
- Cadaver Study

Conclusion:

LeMaitre Vascular has demonstrated that the subject device the 1.5mm HYDRO Expandable LeMaitre Valvulotome is substantially equivalent to the predicate device(s) based on the same intended use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

Lemaitre Vascular, Inc.
Mr. Xiang Zhang
Director of Regulatory Affairs
63 Second Avenue
Burlington, MA 01803 US

Re: K140042
Trade/Device Name: 1.5mm Hydro Expandable Lemaitre Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: Valvulotome
Regulatory Class: Class II
Product Code: MGZ
Dated: March 11, 2014
Received: March 12, 2014

Dear Mr. Zhang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S
2014.04.10 15:12:05 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K140042

Device Name 1.5mm HYDRO Expandable LeMaitre Valvulotome

Indications for Use It is used for the treatment of vascular disorders, and more particularly for excising or disrupting venous valves.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Kenneth J. Cavanaugh -S